SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 6001–6040

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its quality and purity fell below the standard set forth in such compendium.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(c), a word, statement, or other information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the proportion of alcohol contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6001. Quik-Kap Capsules and Rem-Al Emetic. (F.D.C. No. 35122. S. Nos. 36–917 L, 38–356 L.)

INFORMATION FILED: 12–14–53, S. Dist. N.Y., against Leo Savitch, general manager of the Personal Drug Co., and the Rem-Al Drug Co., New York, N.Y.

ALLEGED VIOLATION: Between 9–27–51 and 10–16–51, while a number of capsules of drug were being held for sale at New York, N.Y., after shipment in interstate commerce, the defendant caused the capsules to be repacked into boxes labeled "*Quik-Kap Capsules*" and containing a leaflet entitled "Instruction Leaflet and Order Blank" which act of repacking resulted in such drug in the boxes being misbranded.

In addition, on 9–20–51, the defendant caused to be introduced into interstate commerce, at New York, N.Y., for delivery to Birmingham, Ala., a bottle of *Rem-Al Emetic* which was misbranded.

LABEL IN PART: "QUIK-KAP Capsules For * * * PERSONAL DRUG CO. 6 HESTER ST. NEW YORK 2, N.Y. AVERAGE DOSE * * * ACTIVE

INGREDIENTS: Black Cohosh (Powd. Ext. Cimicifuga) 0.0065 Gm. Wind Flower (Powd. Ext. Pulsatilla) 0.0065 Gm. Ferrous Sulfate U.S.P. Manganese Dioxide Thiamine Hydrochloride U.S.P. (Vit. B_1) 0.001 Gm."; and (front panel "½ OUNCE Rem-Al Emetic Brand of Fluid Extract of Ipecac-Alcohol 30% Distributed by REM-AL DRUG CO. 2 SUFFOLK STREET NEW YORK 2, N.Y."; (back panel) "DIRECTIONS Put 15 to 20 drops of REM-AL in a large drink of alcoholic beverage. Half hour later give a small drink using 15 to 20 drops of Rem-Al. NOTE: Use only as directed above and by directions accompanying bottle. CAUTION: Do not use in heart, liver, kidney, circulatory diseases, pregnancy, stomach ulcers, high blood pressure or serious disorder without consulting your physician."

CHARGE: 502(a)—the labeling of the articles contained false and misleading representations that the *Quik-Kap capsules* were an adequate and effective treatment for delayed or irregular menstruation, and that the *Rem-Al Emetic* was an adequate and effective treatment for drunkenness; and 502(j)—the *Rem-Al Emetic* was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling.

PLEA: Guilty.

DISPOSITION: 1–15–60. $1,000 fine, suspended sentence of 90 days in jail, and probation for 1 year.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6002. Grisovin tablets (2 seizure actions). (F.D.C. Nos. 43172, 43194. S. Nos. 56–794 P, 56–803 P.)

QUANTITY: 3 1,000-tablet btls. at Miami, Fla.

SHIPPED: Between 4–27–59 and 5–4–59, from New York, N.Y., by Overseas Pharmaceutical Co.

LABEL IN PART: "Grisovin 250 Mg. Griseofulvin Glaxo Laboratories, Greenford, England."

LIBELED: 6–19–59 and about 6–25–59, S. Dist. Fla.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 8–17–59. Default—destruction.

6003. Vitamin B_{12} injection. (F.D.C. No. 40930. S. No. 67–040 M.)

QUANTITY: 144 10–cc. vials at Baltimore, Md.

SHIPPED: 9–18–57, from Chicago, Ill., by Maizel Laboratories, Inc.

LABEL IN PART: "Intramuscular 10 cc Intravenous VITAMIN B_{12} INJECTION Cyanocobalamin U.S.P. 1000 mcg. Each cc. contains a sterile solution of 1000 micrograms Vitamin B_{12} U.S.P. (Cyanocobalamin) in normal saline with 2% Benzyl Alcohol as preservative. * * * 28590."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1,039 micrograms of cyanocobolamin (vitamin B_{12}), 9.88 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

LIBELED: 11–1–57, Dist. Md.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States